

AMENDMENT

Serial Number: 10/517,947

Filing Date: October 6, 2005

Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 6
TLK022CON1**REMARKS**

This Amendment is responsive to the final Office Action mailed April 12, 2010. At the time of the Office Action, claims 68-87 were presented for examination.

With this Amendment, independent claim 68 has been amended. Support for the amended claim may be found in the originally filed application, particularly at locations identified hereinafter. Accordingly, Applicant believes no new matter has been added to the application.

Reexamination and reconsideration of the subject application are respectfully requested for at least the following reasons.

Double Patenting

Claims 68-87 stand rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,953,461.

Claims 68-87 stand provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over the pending claims of copending application nos. 10/532,704 and 10/914,650 (now U.S. Patent No. 7,604,635).

As the claims in the present application have not yet been allowed, Applicant respectfully requests that the foregoing double patenting rejections be held in abeyance until the conclusion of prosecution on the merits. Without acquiescing to the properness of the rejections, should the double patenting rejections remain as the only outstanding rejections upon indication of otherwise allowable claims in this application, Applicant is prepared to submit a Terminal Disclaimer to overcome the rejections.

35 U.S.C. §103 Rejections

Claims 68-80, 82-83 and 86-87 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yates et al., U.S. Patent No. 5,810,811 ("Yates") in view of Mulier et al., U.S. Patent No. 6,096,037 ("Mulier"). Claim 81 stands rejected under 35 U.S.C. §103(a) as being

unpatentable over Yates in view of Mulier and further in view of Eggers et al., U.S. Patent No. 5,484,436 ("Eggers"). Claims 84 and 85 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yates in view of Mulier and further in view of Weaver, U.S. Patent No. 5,693,052 ("Weaver").

In response to the Applicant's arguments submitted with the Amendment dated November 18, 2009, the Office Action recites as follows:

Applicant's arguments filed November 18, 2009 have been fully considered but they are not persuasive. Medial is defined as "pertaining to the middle; in or towards the middle." As such, since the tissue grasping surfaces are in the middle of the electrodes since they are located directly beneath of them, as shown best in Figure 6, they are medial to the electrodes. The examiner points to Figure 6, which includes the element numbers in the rejection, and only points to Figures 11-14 and 19 as examples of other configurations. Furthermore, Yates specifically teaches that the first electrode (52) acts as the first pole and is located longitudinally with respect to the jaw member (32). Jaw member (32) also comprises the second electrode (18) which acts as the second pole. Since these electrodes are located longitudinally down the jaw member the electrical current will flow in tissue grasped between the tissue grasping surfaces parallel to the tissue grasping surfaces and across a width of the tissue grasping surface (Col. 6, lines 35-62; Figure 6).

In raising the rejection, the Office Action appears to provide a definition for the word "medial" from an unidentified source. Thereafter, as the Applicant understand the Office Action, the cited art has been construed to teach the feature of "the first jaw tissue grasping surface and the second jaw tissue grasping surface medial to the first electrode and the second electrode" as recited by independent claim 68 where it may be shown in the art that "the tissue grasping surfaces are in the middle of the electrodes...".

Without acquiescing to the properness of the foregoing rejection, and in particular whether the definition of the term "medial" as set forth in the Office Action comports with the Applicant's application, Applicant has elected to amend independent claim 68 to expedite prosecution and further distinguish from the art.

Applicant has amended independent claim 68 to include the features of the first jaw having a first jaw tissue grasping surface and the second jaw having a second jaw tissue grasping

AMENDMENT

Serial Number: 10/517,947
Filing Date: October 6, 2005
Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 8
TLK022CON1

surface, with the tissue grasping surface of each jaw directly opposing each other and comprising an electrically insulative surface. Applicant has also amended independent claim 68 to include the features of the first jaw tissue grasping surface and the second jaw tissue grasping surface medial to the first electrode and the second electrode, and the first electrode and second electrode laterally outside the first jaw tissue grasping surface and the second jaw tissue grasping surface. Support for the amendments may be found, for example, in paragraphs [0097] and [0107] of U.S. Publication No. US2006/116675 A1.

Referring to the cited art, Applicant does not understand Yates to disclose the foregoing features in combination with the remainder of claim 68. Referring to the embodiment of FIG. 6, it appears a tissue grasping surface of each jaw directly opposing each other and comprising an electrically insulative surface as recited by independent claim 68 may be provided by directly opposing surfaces of U-shaped insulating material 55 and cartridge 23. However, in such instance, Applicant does not understand U-shaped first pole 52, which may provide a first electrode, to be laterally outside of the aforementioned directly opposing tissue grasping surfaces, particularly as U-shaped first pole 52 appears to be medial to U-shaped insulating material 55.

Similarly, Applicant does not understand the foregoing features, in combination with the remainder of claim 68, to be disclosed by any of FIGS. 11-14 and 19 of Yates as those are made reference to in the Office Action.

For FIG. 11, Applicant does not understand U-shaped pole 152, which may provide a first electrode, to be laterally outside of directly opposing, electrically insulative, tissue grasping surfaces which may be provided by U-shaped insulator 155 and the cartridge, particularly as U-shaped pole 152 appears to be medial to U-shaped insulator 155.

For FIG. 12, Applicant does not understand either of poles 251, 252 to be laterally outside of directly opposing, electrically insulative, tissue grasping surfaces which may be provided by U-shaped insulator 255 and the cartridge.

For FIG. 13, Applicant does not understand U-shaped pole 352 to be laterally outside of directly opposing, electrically insulative, tissue grasping surfaces which may be provided by U-shaped insulators 355a and 355b.

AMENDMENT

Serial Number: 10/517,947
Filing Date: October 6, 2005
Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 9
TLK022CON1

For FIG. 14, Applicant does not understand either of poles 451, 452 to be laterally outside of directly opposing, electrically insulative, tissue grasping surfaces which may be provided by U-shaped insulators 455a and 455b.

For FIG. 19, Applicant does not understand U-shaped pole 852 to be laterally outside of directly opposing, electrically insulative, tissue grasping surfaces which may be provided by insulator 855 and the cartridge.

Lastly, for FIGS. 17 and 18, as set forth in the Amendment dated November 18, 2009, the electrodes do not appear positioned for the recited electrical current to flow across a width of the tissue grasping surfaces. In FIGS. 17 and 18, it appears, rather, that electrical current would flow longitudinally along a length of the jaws 732, 734.

Turning to the secondary references, Mulier, Eggers and Weaver are not understood by the Applicant to provide the missing teachings of Yates as outlined, *supra*, to maintain a rejection of the claims as being unpatentable under 35 U.S.C. §103(a).

In addition to the missing teachings of the cited art, Applicant believes one of ordinary skill in the art would not combine Mulier with Yates for at least the following reasons.

In turning to the Office Action, after acknowledging Yates fails to expressly state having at least one fluid passage, the Office Action goes on to combine Yates with Mulier with the following rationale:

Mulier et al teaches an analogous tissue grasping device (Figure 2) that is fluid assisted. Mulier et al teaches a fluid-assisted tissue grasping device that comprises a first jaw (44/48) and a second jaw (46/50) and a first electrode (47) and second electrode (49) (Col. 4, lines 34-47 and lines 55-64). Mulier et al teaches at least one fluid delivery passage (52 and 54) and at least one fluid outlet (166) (Col. 4, line 55 through Col. 5, line 12; Col. 5, lines 25-35; Figures 3-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the tissue grasping device, as taught by Yates et al, to be fluid-assisted having a fluid delivery passage and fluid outlet, as taught by Mulier et al, in order to maintain relatively consistent maximal electrical contact areas, substantially prevent hot spots and allow higher power than soft coagulation, and further allows for little to no arcing, cutting smoke or char (Col. 5, lines 53-56).

AMENDMENT

Serial Number: 10/517,947

Filing Date: October 6, 2005

Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 10
TLK022CON1

The Applicant respectfully disagrees that it would be obvious to combined Yates with Mulier as set forth in the Office Action.

Turning to Yates, Yates appears to teach that the compression provided by the device(s) therein provide certain benefits as follows:

It is believed that the tissue compression normalizes tissue impedance by reducing structural differences in tissue which can cause impedance differences. Compression also stops significant blood flow and squeezes out blood which acts as a heat sink, particularly when flowing through blood vessels. Thus, compression optimized delivery of energy to tissue in part by enabling the rate of energy delivery to exceed the rate of dissipation due to blood flow. The arrangement of the electrodes, which make up the poles, is important to ensure that the current passing between the two poles passes through the compression zone. Also, insulation or isolation of the opposite poles from each other on the instrument permits tissue compression without shorting of the instrument poles or electrical arcing common in bipolar instruments. Col. 3, ll. 36-49.

Thus, from the foregoing, Applicant understands that the compression applied by Yates device(s) may provide certain advantages with respect to optimized delivery of energy to tissue, as well as inhibiting heat sinks in the tissue and electrical arcing.

Now, Applicant believes that use of a fluid with Yates as taught by Mulier would be detrimental to use of the device(s) of Yates in light of the feedback system used by Yates to determine when a desired or predetermined degree of coagulation has occurred. Yates provides the following description of the feedback system which operates as follows:

The feedback system may also determine tissue characteristics at or near a coagulation zone which indicate degree of coagulation. The electrical impedance of the tissue to which the electrical energy is applied may also be used to indicate coagulation. Generally, as energy is applied to the tissue, the impedance will initially decrease and then rise as coagulation occurs. An example of the relationship between electrical tissue impedance over time and coagulation is described in Vaellfors, Bertil and Bergdahl, Bjoern "Automatically controlled Bipolar Electrocoagulation," Neurosurg. Rev. p. 187-190 (1984) incorporated herein by reference. Also as desiccation occurs, impedance increases. Tissue carbonization and or sticking to instrument as a result of over application of high voltage may be prevented using a feedback system based on tissue impedance characteristics. Other examples of tissue characteristics which may indicate coagulation include temperature and light reflectance. Col. 9, ll.13-30.

AMENDMENT

Serial Number: 10/517,947
Filing Date: October 6, 2005
Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 11
TLK022CON1

From the foregoing, Applicant believes the Yates feedback system, which may be used to prevent tissue carbonization (i.e. char) and or sticking to instrument, relies upon an accurate determination of tissue impedance.

Now, assuming, *arguendo*, that the device(s) of Yates may be adapted to be a fluid-assisted devices in view of Mulier as set forth in the Office Action, the Applicant believes that the use of the fluid may be expected to adversely effect the ability of the Yates feedback system to accurately determine tissue impedance. In other words, the use of a fluid as taught by Mulier may be expected to inhibit determining tissue impedance as taught by Yates due to its mere presence, in which case the impedance as determined may be expected to result from a combination of the tissue and the fluid (or possibly the fluid alone) as opposed to the tissue itself. Consequently, given the use of a fluid as taught by Mulier may be reasonably expected to render the feedback system of Yates unsatisfactory for its intended purpose, in possibly leading to erroneous impedance determinations, Applicant believes one of ordinary skill in the art would be led away from combining Yates with Mulier.

Moreover, the addition of a fluid to Yates as taught by Mulier would arguably change the principle of operation of Yates as set forth, *supra*. Accordingly, if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Thus, it would appear that to modify Yates in light of Mulier would transgress the rule of *In re Ratti*.

Accordingly, the Applicant believes that it has been demonstrated that claims herein define over the teachings of the cited art. In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are not rendered obvious by the cited art, and the conditions of patentability have been satisfied. Reconsideration and allowance of independent claim 68, as well as the claims which depend directly or ultimately therefrom, is respectfully requested.

AMENDMENT

Serial Number: 10/517,947

Filing Date: October 6, 2005

Title: FLUID-ASSISTED MEDICAL DEVICES, SYSTEMS AND METHODS

Page 12
TLK022CON1**SUMMARY**

The Applicant respectfully submits that, in light of the foregoing amendments and remarks, and having dealt with all the rejections raised by the Examiner, the claims are in order for allowance.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 50-2121.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

Respectfully submitted,

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